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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,535	12/17/2003	Michael G. Tal	TAL-001	4422
21884	7590	03/16/2010	EXAMINER	
WELSH & FLAXMAN LLC 2000 DUKE STREET, SUITE 100 ALEXANDRIA, VA 22314				NGUYEN, VI X
ART UNIT		PAPER NUMBER		
3731				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/736,535	TAL, MICHAEL G.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Victor X. Nguyen	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 October 2009.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 17-20 and 23-44 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 17-20 and 23-44 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/15/2009</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

1. This Office Action is in response to the amendments filed on 10/15/2009.

Claims 17-20 and 23-44 are pending in this present application.

### ***Response to Amendment***

2. Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-19, 23-24, 26, 28-37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg US 5,370,653 in view of Biegeleisen US 5,022,399.

Claims 17, 30, 34: Cragg discloses advancing an elongated intraluminal member 14 through the vein to a treatment site in the vein; moving the intraluminal member against the vein's endothelium at the treatment site to disrupt the endothelium and ensure it is damaged (figures 1, 3, see col. 3, lines 30-67, and col. 4, lines 1-11).

Cragg does not disclose injecting sclerosant into the vein at the treatment site and onto the damaged susceptible endothelium thereby causing it irreversible damage at the treatment site, or the sclerosant is injected during scraping. Biegeleisen teaches the use of sclerosant to treat

venous disorders and varicose veins as well known in the art since 1851 (see col. 2, lines 25-28, col. 10, lines 22-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cragg by injecting sclerosant into the vein at the treatment site and onto the damaged susceptible endothelium thereby causing it irreversible damage at the treatment site, or the sclerosant is injected during scraping as taught by Biegeleisen in order to enhance a better treatment of venous disorders and varicose veins.

Claims 18-19: Cragg discloses the step of scraping the intraluminal member against the endothelium, and wherein the intraluminal member comprises a hollow infusion wire 44, see col. 6, line 66; and the sclerosant is injected into the vein through the hollow infusion wire 44.

Claim 24: Cragg discloses the intraluminal member is advanced through a sheath 32, and the sclerosant is injected into the vein through an annular space 34 between the intraluminal member and the sheath 32.

As to claim 25: Cragg in view of Biegeleisen discloses the invention substantially as claimed except regarding the vein has a size at the treatment site of 2-10mm. It would have been obvious to modify the vein has a size at the treatment site of 2-10mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re. Aller*, 220F, 2d 454, 105 USPQ 233.

Claims 26, 29: Cragg discloses scraping comprises rotating the intraluminal member 14 in the vein under the control of a motor 50 so that a portion of the intraluminal member engages the endothelium (see col. 6, lines 26-28).

Claims 28, 31-33: Cragg discloses the intraluminal member curves at a distal end (at the distal end of 14, bristles are curved, fig. 3); wherein the intraluminal member is rotated and moved longitudinally during scraping., wherein the endothelium of the vein is disrupted without perforating the vein; and wherein moving the intraluminal member comprises moving it longitudinally (col. 6, lines 26-28).

Claim 35: Cragg discloses advancing an elongated intraluminal member 14 through the vein to a treatment site in the vein; activating the intraluminal member against the vein's endothelium at the treatment site to disrupt the endothelium and ensure it is damaged (figures 1, 3, see col. 3, lines 30-67, and col. 4, lines 1-11).

Cragg does not disclose injecting sclerosant into the vein at the treatment site and onto the damaged susceptible endothelium surface with the activation of the intraluminal member, and the steps of activating and injecting result in ablation of the vein. Biegeleisen teaches the use of sclerosant to treat venous disorders and varicose veins as well known in the art since 1851 (see col. 2, lines 25-28, col. 10, lines 22-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cragg by injecting sclerosant into the vein at the treatment site and onto the damaged susceptible endothelium surface and the steps of activating and injecting result in ablation of the vein as taught by Biegeleisen in order to enhance a better treatment of venous disorders and varicose veins.

Claims 36-37: Cragg discloses the step of activating includes moving the intralmninal member 14 against the endothelial surface to cause disruption or irritation of the vein; and wherein the intraluminal member comprises an infusion wire (col. 6, lines 4-5).

Claims 39-41: Cragg discloses wherein the step of activating includes disrupting or irritating the endothelial surface of the vein wall of the vein in a manner creating spasm of the vein; wherein the intraluminal member 14 is protected by a sheath 30, and the step of activating includes withdrawing the sheath to expose the intraluminal member to the vessel and vessel wall; wherein the step of withdrawing the sheath 30 is done before disrupting or irritating of the endothelial surface of a vein wall of the vein.

Claims 42-44: Biegeleisen teaches the step of injecting sclerosant is performed during activating the intraluminal member for disrupting or irritating the endothelial surface of the vein wall; and wherein the step of injecting sclerosant is performed before activating the intraluminal member for disrupting or irritating the endothelial surface of the vein wall (see col. 2, lines 25-28; col. 10, lines 22-67).

Claims 20, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg in view of Biegeleisen as applied to claim 17 above, and further in view of Duffy et al 6,048,332.

Cragg in view of Biegeleisen disclose the invention substantially as claimed. However, they fail to disclose the elongated intraluminal member is a balloon catheter. However, Duffy et al teach the elongated intraluminal member is a balloon catheter (fig. 2a, element 10 is an intraluminal member which has a balloon 20 is positioned at the distal end of the intraluminal member). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intraluminal member of Cragg in view of Biegeleisen with the intraluminal member is a balloon catheter as taught by Duffy in order to allow fluid that passes through the conduit out of the balloon (col. 8, lines 19-28).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg in view of Biegeleisen as applied to claim 26 above, and further in view of Groshong US 5,074,871.

Cragg in view of Biegeleisen disclose the invention substantially as claimed. However, they fail to disclose the intraluminal member that engages the endothelium is sharpened. However, Groshong teaches the disruptor 35, fig. 3 is sharpened (sharpened edge 60, col. 6, lines 53-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intraluminal member of Cragg in view of Biegeleisen with the intraliminal member that engages the endothelium is sharpened as taught by Groshong in order to cut a strip of plaque from the interior wall of a vessel, and cutting free the side without tearing the tissue.

Claims 17, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over R.A. Williams et al (Vol. 119, No. 11, November 1984) in view of Cragg US 5,370,653.

Claims 17 and 35: R.A. Williams et al (please see the entire article) disclose a similar method which includes injecting sclerosant into the vein at the treatment site causing irreversible damage to the disrupted lining endothelium at the treatment site and consequently stimulating fibrosis of the vein at the treatment site, thereby permanently occluding the vein (Vol. 119, No. 11, November 1984, see second column, second paragraph , page 1284 “The complication of modern sclerotherapy are as follows: localized venous **thrombosis**..., and the forth paragraph “The sclerosant sodium tetradecyl sulfate has detergent qualities that produce **venous intimal damage**, which is followed by **thrombophlebitis**”). It is noted that thrombosis is defined “the formation or presence of a blood clot within a blood vessel”. Furthermore, thrombophlebitis is defined “inflammation of a vein with formation of a thrombus” as evidenced by “Merriam-

Webster online dictionary". Thus, **thrombosis** or **thrombophlebitis** would cause some degree of occluding the vein. Moreover, the degree of occlusion is not being claimed.

R.A. Williams et al do not disclose advancing an elongated intraluminal member through the vein to a treatment site in the vein; moving activating the intraluminal member against the vein's endothelium at the treatment site to disrupt the lining.

Cragg teaches advancing an elongated intraluminal member through the vein to a treatment site in the vein; moving activating the intraluminal member against the vein's endothelium at the treatment site to disrupt the lining.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify R.A. Williams et al by advancing an elongated intraluminal member through the vein to a treatment site in the vein; moving activating the intraluminal member against the vein's endothelium at the treatment site to disrupt the lining as taught by Cragg in order to enhance the effectiveness of better treatment of venous disorders and varicose veins.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US. Pat. No. 7,083,643 to Whalen. Pub. No. US 2003/0004568 to Ken.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VN /  
Examiner, Art Unit 3731  
3/11/2010

/Gary Jackson/  
Supervisory Patent TC  
TC 3700  
March 14, 2010